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MODELLING OF THE NEEDLE-PALISADE FIXATION SYSTEM FOR THE TOTAL HIP RESURFACING ARTHROPLASTY ENDOPROSTHESIS

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ABSTRACT: In this paper there is presented the geometrical model of the endoprosthesis with needle-palisade fixation system for minimal invasive total hip resurfacing arthroplasty (THRA) corresponding with the concept and assumptions of the Rogala's patent [16, 17], also presented in papers [14, 15]. The most advantageous needle-palisade fixation system variant according to adhesive properties optimization is here under discussion. Authors also present early pre-prototypes of the endoprosthesis manufactured by CNC Controlled Electrical Discharge Machining and Selective Laser Melting with discussion about the technological possibilities for the further endoprosthesis prototypes manufacturing.

KEY WORDS: joint replacement, bone-implant fixation, low invasive arthroplasty

1. INTRODUCTION

The total hip resurfacing arthroplasty concept (THRA) is the epiphyseal cancellous bone preserving alternative to commonly used long stem total hip replacement (THR). It restores normal joint biomechanics and close-to-natural load transfer ensuring artificial joint stability. During the traditional THR with the long stem endoprosthesis (Fig. 1a) the head and neck of the femur are removed. To the femur cavity there is inserted the metallic stem while the cup is placed into the socket in pelvis which has been reamed to shape. Both components of endoprosthesis are bonded to surrounding bone by either bone tissue in-growth or with polymer cement. The high invasiveness of traditional endoprosthesis leads to non-physiological load transfer (stress shielding phenomenon) resulting in bone atrophy and extensive destruction of surrounding bone tissue (Fig. 1b).

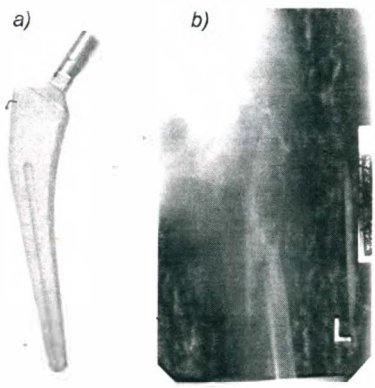


Fig. 1: a) Traditional long-stem hip endoprosthesis; **b)** the roentgenogram showing the destruction in femoral bone with bone resorption caused by the stress shielding phenomenon

In case of hip resurfacing hip arthroplasty the femoral head and neck are preserved. The joint articular surfaces of the head and socket are machined away with precision instruments with 3–4 mm of bone below being removed. The concept of THRA allows transferring load in the artificial hip joint in a way close to natural – through the head and neck of the femur and along the femoral shaft. The overall stability of the hip joint is improved and the stemless femoral component saves proximal bone stock for later revision [20].

Historically the early resurfacing endoprostheses have been made with various design and materials, e.g.: Smith's (1917), Smith-Petersen's (1923), Willey's (1938), Albee and Pearson's (1940-1944), Urist's (1951), Laing's (1960) [7, 12, 20, 21]. In these designs the bearing surfaces like metal-on-metal, plastic- or ceramic-on-metal and ceramic-on-ceramic were used, but all of these couples failed in short term due the surgical issues, lack of permanent fixation or loosening of the endoprosthesis components, necrosis, deformation with high friction, rapid wear and intense tissue reaction to wear particles. All these projects were abandoned mainly for reasons of the materials (Teflon®, celluloid, bakelite, Pyrex® glass, polyethylene) and the used technique of fixation [10]. In the 1960's and early 1970's many resurfacing systems have been designed and implanted by Charnley (1961), Müller (1968) (Fig. 2a), Wagner and Freeman (1976) and others achieving promising early results, but failure rates up to 35% at longer follow-up [8]. The failures were due the acetabular and femoral components loosening, vascular necrosis of the femoral head and neck and the femoral neck fractures [10]. Because of the clinical results this generation of hip resurfacing systems also were abandoned in mid 1980's. The philosophy of resurfacing arthroplasty has its renaissance since early 1990's. First who came up and presented results from MoM resurfacing was McMinn (1991), being precursor for both Cormet Resurfacing Hip System and Birmingham Hip Resurfacing System, see Fig 2b. At the same time Amstutz began series of developments which culminated in,the Converse Plus Hip Resurfacing System [9]. Those modern endoprostheses differ from it's predecessors in terms of materials, fixation technique, component thickness and size options. The suggested advantages of those implants are stronger fixation, lower wear bearing, better bone conservation and lower risk of complication, especially fracture and dislocations. Their clinical studies showed wider and most interesting data on follow-ups and surface implants survival [1, 5].

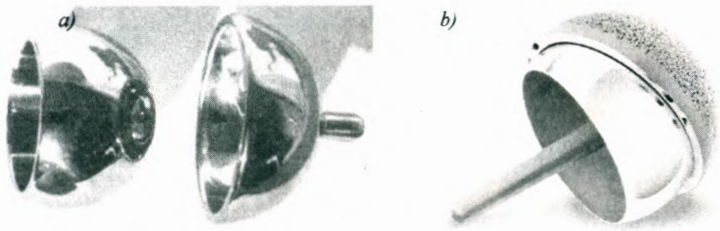


Fig. 2: a) Müller's (1968) MoM resurfacing [20]; **b)** Birmingham Hip (BHR) Implant [5]

However, other studies showed also examples of the modern resurfacing hip arthroplasty complications [2, 18, 19]. After more than 15 years of the third generation resurfacing history there can be seen the division between the THRA supporters [10] and objectors [9]. These facts justify the necessity of the research on new material applications and new fixation system design for THRA. In the currently used THRA endoprosthesis BHR (Fig. 2b), the acetabular component is cementless, while the femoral one is cemented. The first *totally cementless* fixation endoprosthesis for THRA was presented by Rogala [16, 17]. He proposed the original needle-palisade fixation system for THRA and other joints. Design of the fixation system for cementless THRA, as a part of the problem of biomechanical construction of endoprostheses for cementless total arthroplasty of human hip and other joints, is the subject of the research project no 4 T07C 056 29 (MNiSW, Polish Ministry of Science) carried out in cooperation between the University of Medical Sciences in Poznan (Spine Surgery, Orthopaedics and Traumatology Department), Poznan University of Technology (Chair of

Machine Design Fundamentals) and the Kazimierz Wielki University in Bydgoszcz (Department of Fundamentals of Medical Bioengineering, Institute of Technology).

2. THE ROGALA'S THRA ENDOPROSTHESIS PRE-PROTOTYPES

In Fig. 3 there is presented the early pre-prototype of the Rogala's THRA endoprosthesis manufactured by CNC Controlled Electrical Discharge Machining (EDM) with the wire electrode.

Fig. 3: The pre-prototypes of THRA endoprosthesis manufactured by Controlled Electrical Discharge Machining (EDM)

In Fig. 4 there is presented the 3D geometrical model of the endoprosthesis and the whole endoprosthesis pre-prototype manufactured by Stereolitography (SLA) technology.

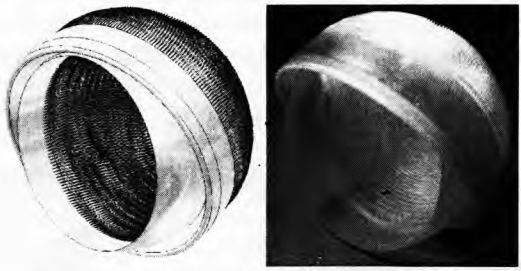


Fig. 4: The geometrical model and pre-prototype of Rogala's THRA endoprosthesis

The comparison of the reconstruction precision of needle-palisade fixation system from CAD models by the two technologies is indication for the adequate technology selection for the future serial product. In authors opinion, the CNC Controlled Electrical Discharge Machining doesn't perform sufficiently the requirements for the precision in reconstruction of needles. Much more possibilities can be provided by technologies from RP group. If metal is the material choice for serial product, the direct metal manufacturing (DMM) is best one from the group. One of mostly predisposed technology from the DMM group is Selective Laser Melting (SLM) developed by Fraunhofer Institute for Laser Technology and commercialized by F&S Stereolithographietechnik GmbH [3].

The SLM process is based on a principle in such manner that the powder is applied in very thin layers on a building platform and melted due to the thermal influence of a laser beam. The powder particles have a statistical distribution of size from 5 to 20 or to 50 μm. Each layer the laser beam generates the outline of the part that is being built by melting the powder particles, before the building platform is lowered and coated with a new layer of powder [13]. SLM is one of the possible processes to manufacture 3D metallic structures using a variety of material options, including biocompatible titanium and chromium-cobalt alloys with full serial characteristics and typically great freedom of

geometric design and also have successful medical applications [6]. In Fig. 5 there is presented the sample of needle-palisade fixation system manufactured of Ti6Al4V alloy with SLM technology.

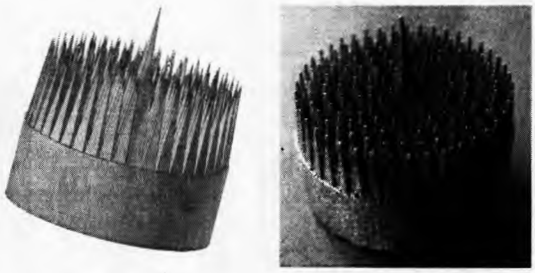


Fig. 5: Sample of the needle-palisade fixation system manufactured with SLM technology of Ti6Al4V

Various configurations of similar samples of needle-palisade fixation system with equilateral triangles and squares in pyramid's bases arranged concentrically (H:R ratios 5:1, 7:1, and 9:1 and various pyramid's base area from 0,5 to 2 mm^2) have been selected for further biomechanical tests. It will be manufactured by SLM. The selection of biomaterials for the THRA endoprosthesis prototypes for preclinical tests is still under discussion. SLM offers universally used biomaterials for implants elements like Ti6Al4V, Ti6Al7Nb or CoCrMo alloys. The best biomaterial selection for needle-palisade fixation system is Ti6Al7Nb because of closer to bone mechanical properties of Ti-based alloys and higher biotolerance of Niobium in comparison to Vanadium as an alloys additions. Ti alloys are never the first choice of material in MoM articulation, so CoCrMo coated with Titanium Niobium (Oxy) Nitrite (TiNbN) is considered as the compromising alternative for the Ti alloys on endoprosthesis articulating surfaces in order to obtain optimal resistance against wear.

3. THE ADHESIVE SURFACE ENLARGEMENT INDEX AS A CRITERION FOR NEEDLE-PALISADE FIXATION SYSTEM OPTIMIZATION

In case of traditional cementless endoprostheses with porous coatings the adhesive properties of implant porous surface [24] are one of very important factor for its successful fixation by bone tissue ingrowth. These properties can be estimated in case of porous implant by the index of the enlargement of the adhesive surface of bone-implant interface ψ [11, 22]. The adhesive surface enlargement index ψ indicates the improvement of implant adhesive properties by roughening its surface with porous coating in relation to the smooth implant. For typical plasma spraying porous coated femoral component the value of this ψ index is about 1.5 [23, 25]. The needle-palisade fixation system invented by Rogala [16, 17] and presented in several papers [14, 15] assumes the increase of the index ψ value up to 7 and more. The new needle-palisade fixation system aims to possibly maximal extension of the adhesion contact between bone and implant in case of both components of the endoprosthesis the femoral and the acetabular. It is assumed that the adhesion surface of bone-implant interface will be modelled optimally from the point of view of the biomechanical fixation forces and stress-strain distribution in bone around implant [14].

The most advantageous needle variant for needle-palisade system of Rogala's endoprosthesis was investigated during the mathematical analyses of adhesive surface enlargement index ψ for the pyramids with various regular polygons in the pyramid base and for cone. All pyramids have H:R ratio 5:1 and pyramid base area equal 1 mm^2, where H is the height of the pyramid, R is a radius of the circumcised circle about a pyramid base. The Fig. 6 presents the results for equilateral triangle, square, hexagon, octagon, decagon in the pyramid base and for cone.

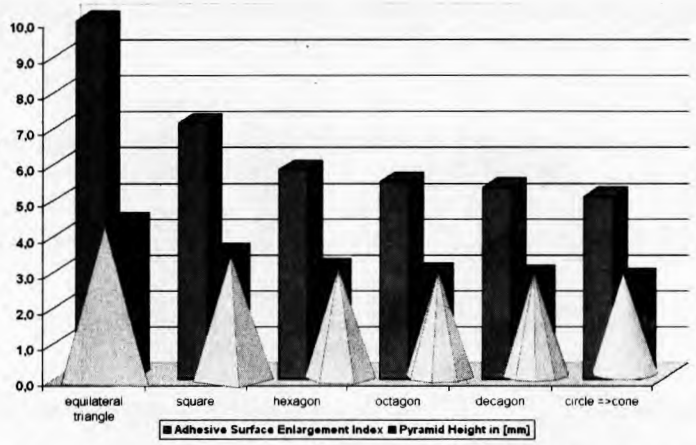


Fig. 6: Diagram of the adhesive surface enlargement index ψ values for various pyramid variants in needle-palisade fixation system in Rogala's THRA endoprosthesis

As can be seen on the above diagram the most advantageous values of the adhesive surface enlargement index ψ have been obtained for the pyramids with equilateral triangle and square in pyramid base. The same tendency is maintained if the H:R ratio is increased from 1:1 to 9:1 as it is shown in Fig. 7. On the basis of the adhesive surface enlargement index ψ analyses for various single pyramids the ones with equilateral triangle and square in base were chosen for further analyses.

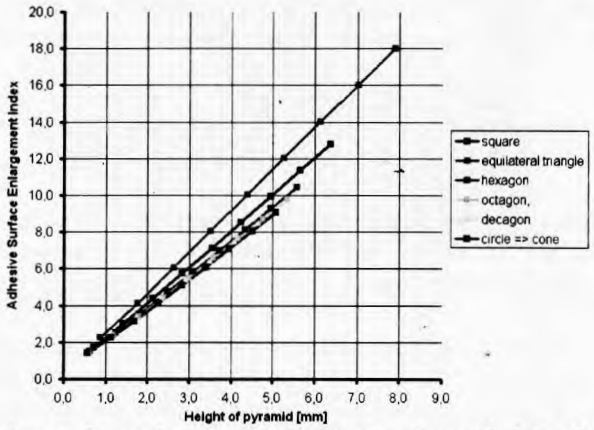
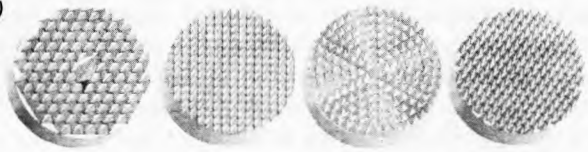


Fig. 7: Adhesive surface enlargement index in function of height of pyramid

The next step was the analyses from the point of view of the ψ index of 4 proposals of needles pyramids arrangements (equilateral triangle, square and hexagon in base) presented in Fig. 8a located within the circle boundary (Ø = 16mm, 32mm and 48 mm). The values of the ψ index arrangement for the proposed arrangements are presented on the diagram in Fig. 8b.

a)



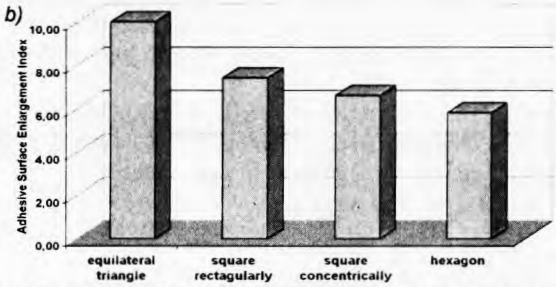


Fig. 8: a) Proposals of needle-palisade fixation system arrangements (samples): (from left to right) equilateral triangles, squares rectangular, squares concentrically and hexagons; **b)** The values of the adhesive surface enlargement index for the presented arrangements

4. CONCLUSIONS

The results of the above analyses suggest to choose for further analyses the pyramid with the equilateral triangle and the rectangular located squares arrangements. The analyses of structural compatibility of the needle-palisade arrangements with trabecular bone from human and animal femur head will be consecutive criterion for the pyramid's base area and H:R ratio and most advantageous needles arrangements final settlement for needle-palisade fixation system of Rogala's THRA endoprosthesis. These parameters will be also verified biomechanically during the laboratory biomechanical investigations on endoprosthesis insertion conditions (the push-in forces determining and appraisal of the destruction zone in bone-implant interface region) and on the strength of the bone substitute-implant fixation with the endoprosthesis elements.

5. REFERENCES

[1] AMSTUTZ, H.C., BEAULÈ, P.E., DOREY, F.J., LE DUFF, M.J., CAMPBELL, T.A., GRUEN, T.A, Metal on Metal hybrid surface arthroplasty: two to six year follow-up study. J. Bone Joint Surg. Am. 2004; 86-A, p. 28.

[2] AMSTUTZ, H.C., CAMPBELL, P.A, LE DUFF, M.J.: Fracture of the neck of the femur after surface arthroplasty of the hip. J. Bone Joint Surg. Am. 2004; 86-A:1874–1877.

[3] BEAMAN, J.J., ATWOOD, C., BERGMAN, T.L., BOURELL, D., HOLLISTER, S., ROSEN, D.: Additive/subtractive manufacturing research and development in Europe. The World Technology Evaluation Center, Inc. Panel Report, December 2004, http://www.wtec.org/additive/report/additive-report.pdf.

[4] Birmingham Hip Resurfacing System, http://www.hipresurfacing.com/

[5] DANIEL, J., PYNSENT, P.B., McMINN, D.J.W.: Metal-on-metal resurfacing of the hip in patient under the age of 55 years with osteoarthritis. J. Bone Joint Surg. Br. 2004; 86-B:177–184.

[6] DIRK, A., HOLLANDER, D.A., WIRTZ, T., VON WALTER, M., LINKER, R., SCHULTHEIS, A., PAAR, O.: Development of Individual Three-Dimensional Bone Substitutes Using SLM, Eur. J. Trauma 2003; 4:228–234.

[7] HARLAN, C., AMSTUTZ, M.D.: History of Hip Resurfacing, http://www.jri-oh.com/

[8] INDELLI, P.F., VEINS, N., DOMINQUES, D., KITOAKA, K., PARKER VAIL, T.: In vitro biomechanical properties of a hip resurfacing system. In: BENAZZO, F., FALEZ, F., DIETRICH, M., (Eds): Bioceramics and Alternative Bearings in Joint Arthroplasty – Proc. 11th BIOLOX® Symp., Rome, June 30th-July 1st, 2006, Darmstadt, Steinkopff Verlag, 2006, p. 47.

[9] LACHIEWICZ, P.F.: Resurfacing arthroplasty: Time to consider it again? No. AAOS 2006 Annual Meeting Proceedings, 2006, p. 77.

[10] MANGE, M.: Seven years of experience in MoM resurfacing: Results and open questions. In: BENAZZO, F., FALEZ, F., DIETRICH, M., (Eds): Bioceramics and Alternative Bearings in Joint Arthroplasty – Proc. 11th BIOLOX® Symp., Rome, June 30th-July 1st, 2006, Darmstadt, Steinkopff Verlag, 2006, p. 23.
[11] MIELNICZUK, J., UKLEJEWSKI, R., WINIECKI, M., ROGALA, P.: The poroparameters for evaluation of structural-osteoinductive and mechanical properties of bone-implant porous coating interface. Part 1. J. Biomech. 2006; 39 Suppl. 1, p. S14.
[12] PELTIER, L.F.: A history of hip surgery. In: CALLAGHAN, J.J., ROSENBERG, A.G., RUBASH, H.E., (Eds): The Adult Hip. Philadelphia, New York: Lippincott-Raven Publishers, 1998, p. 3.
[13] REHME, O., EMMELMANN, C.: Reproducibility for properties of Selective Laser Melting products, Proceedings of the 3rd Intern. WLT Conf. on Lasers in Manufacturing 2005, Munich, June 2005.
[14] ROGALA, P., UKLEJEWSKI, R., WINIECKI, M., MIELNICZUK, J., AUGUŚCIŃSKI, A.: The concept and geometrical model of modern endoprosthesis concerning minimal invasive total hip resurfacing arthroplasty (THRA). Proc. 11th Intern. Conf. COSIM'2006, Krynica Zdrój, Poland Aug 30th–Sept 1st, 2006, Wyd. Polit. Warsz., Inst. Podst. Bud. Masz., 2006, p. 265.
[15] ROGALA, P., UKLEJEWSKI, R.: Needle-palisade fixation for total resurfacing arthroplasties of hip and other joints - Biomechanical principles, J. Biomech., 39, Suppl. 1, 2006, p. S513.
[16] ROGALA, P.: European patent nr 072418 B1: „Endoprothesis".
[17] ROGALA, P.: USA patent nr 5,91,759: „Acetabulum endoprothesis and head".
[18] SHIMMIN, A.J., BACK, D.: Femoral neck fractures following Birmingham hip resurfacing: a national review of 50 cases. J. Bone Joint Surg. Br. 2005; 87-B:463–464.
[19] SHIMMIN, A.J., BARE, J., BACK, D.L.: Complications associated with the hip resurfacing arthroplasty. Orthop. Clin. North Am. 2005; 36: 187–193.
[20] STREICHER, R.M. Hip resurfacing – a superior articulation concept? In: BENAZZO, F., FALEZ, F., DIETRIC/H, M., (Eds): Bioceramics and Alternative Bearings in Joint Arthroplasty – Proc. 11th BIOLOX® Symp., Rome, June 30th-July 1st, 2006, Darmstadt, Steinkopff Verlag, 2006, p. 39.
[21] UKLEJEWSKI, R., ROGALA, P., MIELNICZUK, J., STRYŁA W.: Współczesne trendy w konstruowaniu małoinwazyjnych endoprotez stawów układu kostnego człowieka - na podstawie nietradycyjnego porosprężystego modelu biomechanicznego kości. In: Malujda I., (Ed): Kierunki projektowania i badania cech konstrukcyjnych elementów maszyn. Wyd. Polit. Pozn. KPKM, 2006, p.217.
[22] UKLEJEWSKI, R., WINIECKI, M., CZAPSKI, T., ROGALA, P., MIELNICZUK, J.: Investigations of microstructure of porous coated orthopaedic implants in the aspect of the structural-adaptive compatibility of bone-porous implant interface. Part 2. Trans VŠB-TU Ostrava, Metallurg Series 2005;48:267–273.
[23] UKLEJEWSKI, R., WINIECKI, M., MIELNICZUK, J., AUGUŚCIŃSKI, A., ROGALA, P.: Experimental investigations on the structural-osteoinductive properties of porous coatings on orthopaedic implants. Proc. 11th Intern. Conf. COSIM'2006, Krynica Zdrój, Poland, Aug 30th–Sept 1st, 2006, Wyd. Polit. Warsz., Inst. Podst. Bud. Masz., 2006, p. 357.
[24] UKLEJEWSKI, R., WINIECKI, M., ROGALA, P.: On the structural-adaptive compatibility of bone with porous coated implants on the base of the traditional one-phase and the modern two-phase poroelastic biomechanical model of bone tissue. Engng. Biomat. 2006; 54-55:1–13.
[25] WINIECKI, M., AUGUŚCIŃSKI, A., ROGALA, P., MIELNICZUK, J., UKLEJEWSKI, R.: The poroparameters for evaluation of structural-osteoinductive and mechanical properties of bone-implant porous coating interface. Part 2. J. Biomech. 2006; 39 Suppl. 1, p. S469.